TOBACCO-RELATED DISEASE RESEARCH PROGRAM

Pilot Community-Partnered Participatory Research Award (CPPRA)

Introduction

TRDRP has a 20-year history of funding community-based participatory research (CBPR) through the Community and Academic Research Award (CARA) and School Academic Research Award (SARA) grant mechanisms, which required close collaborative partnerships between members of community-based organizations (CBOs), community members, school educators, and academic researchers or community-oriented research scientists. The CARA and SARA grants produced meaningful findings that typically assessed gaps and indicated the need for improved tobacco control prevention and treatment interventions in California; however, there was minimal intervention development.

We have re-envisioned this grant type, emphasizing longer-term thinking and plans that sustain and translate the benefits from the pilot-phase research to the development of new interventions or the enhancement of existing evidence-informed interventions. The expectation is that interventions resulting from these awards will focus on community- or school-based tobacco prevention and/or cessation, as well as practice, program or policy change. We also emphasize the importance of community benefit in tobacco control research, cultural humility, and mutual (community and academic) capacity building for a sustained equitable partnership beyond the life of the grant.

Award Purpose

This award supports a two-year, pilot research grant to build equitable and sustainable partnerships in order to plan and conduct meaningful research that will impact community- or school-level tobacco use and inform evidence-based prevention and treatment programs and interventions or contribute to practice/policy changes in California clinics, schools, institutions, and/or communities. This grant type has multiple requirements, including a collaborative, equitable research partnership comprised of a Community Co-Principal Investigator (Co-PI) and Academic Co-PI with guidance from a Community Advisory Board (CAB) to gather preliminary data or demonstrate proof-of-concept for a tobacco-related research question of importance to the community of interest and that advances science or informs policy. There must be a clearly stated intention and plan to sustain the community-academic partnership; plans to apply for follow-on funding after the pilot funding expires; plans to develop a research-informed, community-forward prevention or treatment intervention; and/or contribute to tobacco-related practice, policy, or program/service enhancement in communities, schools, or clinics.

Community-Partnered Participatory Research Award at TRDRP

Background

Community-academic research partnerships can substantially enhance the quality, reach, and impact of tobacco-related prevention and treatment interventions and regional policy efforts.

Collaborative research teams that include perspectives and contributions from the community of interest have the potential to produce meaningful findings, buy-in among community members, adoption of evidence-informed practice and policy change by organizations serving the community, and ultimately reduce or eliminate tobacco-related health disparities.

We are seeking research that grows out of community interests and is grounded in equitable partnership and leadership from community and academic groups. It is called by various names such as action research, community-based participatory research (CBPR), participatory action research, and community-partnered participatory research (CPPR). In this request for applications (RFA) calling for Community-Partnered Participatory Research Award (CPPRA) applications, the term CPPR is used to highlight the importance of genuine partnership which is the intention of this community-academic award type.

Community is defined as a group of people who share a common element, such as race/ethnicity, age, gender, sexual orientation, gender identity, culture, mental health status, disease status or risk, disability, socioeconomic status, geographical region, or organizational affiliation.

Resources to Understand Community-Partnered Participatory Research

The literature references in this section are included to provide examples of the types of successful CPPR conducted in the United States. This is included to provide examples of power sharing in research, how community benefit from research can be described in a publication, evaluation approaches of community-academic partnerships, and to convey the spirit of this type of research.

The community-partnered participatory research (CPPR) model https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4841676/ was developed by Healthy African American Families, with the support of the Centers for Disease Control and Prevention, and Charles R. Drew University of Medicine and Science.

The academic journal *Ethnicity & Disease* has multiple examples of good CPPR reported in publications in their Volume 28 (2018) supplement 2: Advances in Community-Partnered Participatory Research: Behavioral Health and Beyond. You can view all publications for free (open access) in this special supplement https://www.ethndis.org/edonline/index.php/ethndis/issue/view/34.

The spirit of the CPPR model means the community and academic investigators collaborate in all aspects of the research process, including:

- Identifying and developing the research question(s),
- Transforming community concerns into research questions
- Working closely with a CAB
- Writing and submitting the research proposal
- Developing a plan for sustainability beyond the proposed project
- Designing and implementing the research project
- Analyzing and interpreting findings
- Preparing and submitting progress reports to the funder

- Co-authoring summaries for communities, scientific papers, and presentations
- Disseminating results to community and scientific audiences for collective impact in the community

To reach the level of collaboration described above, a community-academic team must:

- Pay attention to the development and health of the collaborative relationship
- Develop and engage in an equitable shared decision-making process and collaborative plan
- Engage with a CAB that includes representation from the community of interest
- Develop a mutually agreeable plan for sharing power, decision-making, budget and other resources, work of the project, and data
- Ensure that the budgets for community and academic partners are equitable and adequate for the activities assigned to each partner
- Promote opportunities for the community and academic members of the team to contribute to manuscripts prepared for publication and reports for community and policymakers
- Develop and implement dissemination/communication strategies that are sensitive to the culture, experiences, and needs of the community

Conducting CPPR requires a commitment to eliminating power differences between Co-PIs so that they are equal partners. Strong CPPR teams commit to engaging in bi-directional learning among the community and academic members of the team. This builds capacity for future engagement in CPPR for community and academic organizations involved in the project.

CPPRA Key Components & Requirements

This funding opportunity announcement will follow the TRDRP Call for Applications timeline. Application materials are due March 5, 2020 at 12 pm PDT. See **KEY DATES** for this award type for additional information. Specific elements of the award type are detailed below:

- Maximum award amount per year: $200,000 (direct costs)
- Maximum duration: 2 years
- Allowable direct costs: Salaries, fringe benefits, supplies, participant incentives, sub-contracts, equipment, travel, publications and other dissemination activities
    - Travel line items must include project-related travel (As needed; must be fully justified); travel to TRDRP conference: $750 for community Co-PI, $750 for academic Co-PI; other scientific conference travel: $2,000 per year for community Co-PI, $2,000 per year for academic Co-PI
    - Subcontracts are allowed for each of the Co-PIs organizations; must be fully justified
- Indirect costs: Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 30% (or 26% for off-campus investigators).
- One project with two budgets: TRDRP will issue a split-budget award. One budget will be prepared by and awarded to the community Co-PI's organization or institution and a second budget will be prepared by and awarded to the academic Co-PI's organization or institution.

- One organization will be responsible for officially submitting grant materials. It is up to the applicant research team to decide if the community Co-PI's or academic Co-PI's institution will officially submit the grant application.

Future Full CPPRA Grant Type

Although the current CPPRA funding opportunity focuses on pilot phase research questions and allows for the building and strengthening of community-academic partnerships, TRDRP plans to offer a CPPRA funding opportunity that will request applications for fully developed partnerships and research plans (i.e., studies based on preliminary data and complex study designs) in future TRDRP grant cycles. The pilot CPPRA research should gather preliminary results or demonstrate proof-of-concept to support the feasibility of a more developed community-partnered research project, or use scientifically rigorous methods to evaluate existing tobacco prevention and treatment programs in communities or schools.

TRDRP Priority Areas

All grant proposals submitted under this grant type must address at least one TRDRP research priority. Please review online materials about TRDRP's current research priorities, located here http://trdrp.org/research-priorities/index.html and summarized below:

1. Social and behavioral prevention and treatment
2. Cancer prevention, treatment and biology
3. Cardiovascular and cerebrovascular diseases
4. Environmental exposure and toxicology
5. Neuroscience of nicotine addiction and treatment
6. Oral diseases and dental health
7. Pulmonary biology and lung diseases
8. State and local tobacco control policy research
9. Other tobacco-related health effects

Eligibility for Pilot CPPRAs

The submitted pilot CPPRA proposal must include leadership from a team that includes one community Co-PI and one academic Co-PI. Each pilot CPPRA can have only one Co-PI representing the community side and one Co-PI representing the academic side. If there is a need for other close collaborators they can be designated in Key Personnel as a Co-Investigator, consultant, or collaborator.

Qualifications and Requirements for the Community and Academic Partners

In preparing their application, CPPRA community Co-PIs and academic Co-PIs should pay special attention to the elements described below.

Please note: In funded CPPRA's there will be two separate budgets: one budget for the Academic Co-PI managed by their university or institution and a separate budget for the

Community Co-PI managed by their institution or organization. Each partner can have subcontracts linked to their budget.

One organization will be responsible for officially submitting grant materials. It is up to the applicant research team to decide if the community partner's institution or academic partner's institution will officially submit the grant application.

Community Co-PI and Partnering Community-Based Organization (CBO)

The community Co-PI represents the community organization and acts as the lead community researcher. The community Co-PI must have a managerial or higher-level decision-making role within their respective CBO. For the CPPRA award type, the Community Co-PI will be responsible for managing their budgeted expenses while their CBO will be responsible for the fiscal administration of the community research budget as a whole. A California-based CBO must be named in the application submission. Even if an organization is identified as closely engaged in the community partnership, a lead person working at the organization must be named. The CBO must name and formerly approve an individual within their organization to serve as the Community Co-PI for this award type. A letter of support is required from the community applicant's governing body or minutes of the meeting where the board signed off on participation, indicating their review and agreement with the details described in the Collaborative Agreements form.

The qualifications of a community partner:

- Based in California
- Affiliated with an organization, nonprofit community-based group, or institution (e.g., they cannot be a lone person who is not connected to relevant community-based groups)
- Committed to representing the views of their community (not just their own views)
- Have the support of their organization, nonprofit, or institution in order to serve as a Co-PI for the project (we require minutes of the meeting where the board signed off on participation, letter from board chair indicating support for Co-PI participation.
- There is not a requirement for a degree

A community partnership can also involve entities such as school districts, school educators and administrators, educational support service agencies, county health departments, health care providers, hospitals, outpatient clinics, faith-based organizations, and other nonprofit CBOs. Partnerships that involve county health departments, state agencies, and schools or school districts should consider practical issues related to the bureaucracy and inherent structure of these entities, which can hinder a true, equitable partnership. Strategies to promote partnership within busy, under-resourced and hierarchical organizations should be discussed in your grant application.

Academic Co-PI and Partnering Academic Institution

The academic Co-PI should have research expertise and publications related to the research questions in the proposal and a commitment to developing or enhancing an existing program of research focused on community-partnered participatory research. For the CPPRA award type, the

Academic Co-PI will be responsible for managing their budgeted expenses while their university or research institution will be responsible for the fiscal administration of the academic research budget as a whole. An academic partner must be named and their California-based university or research institution must be named in the submitted application.

The qualifications of an academic partner:

- Based at a California academic or nonprofit research institution
- Has a university faculty appointment or a community-oriented research scientist with an appointment at a community-based or private research institution
- Research scientists and community-oriented academics working at a non-university research organization that is a nonprofit can serve in this role
- Must have PI status. PI status permits the academic applicant access to their institution's infrastructure support for managing research grants.
- Committed to conducting long-term community-partnered participatory research
- Committed to accurately depicting the state-of-the-science for the community's benefit

School-Based Research Partnerships

Given the alarming use of electronic nicotine devices, flavored tobacco, and cannabis-tobacco co-use among adolescents, research scientists and faculty are encouraged to partner with schools, school districts, educators, youth peer leaders, and educational support organizations to better understand adolescent tobacco use and co-develop tobacco prevention and cessation curricula for school settings. Many schools and school districts are particularly challenged to fully engage in community-partnered participatory research. Careful attention must be placed on the unique challenges in conducting research in the school environment. Having a teacher as a community Co-PI is likely not feasible given the multiple demands and structure in schools; however, detailed efforts to overcome bureaucratic challenges can be described if a research project will involve close collaboration with schools or school districts. A CBO that provides organizational support and services in educational settings might be better equipped to support school-based research and provide staff time as a community Co-PI. A letter of collaboration from schools or their district should be included, as reviewers will assess the level of commitment and capacity of schools and school districts to engage in the proposed research.

RESEARCH PARTNERSHIP

Community Advisory Board

Each project is required to constitute a Community Advisory Board (CAB). The purpose of the CAB is to provide feedback on all phases of the project. The CAB should be comprised of individuals with expertise in tobacco control and other areas relevant to the project who can provide helpful feedback on both the community and scientific aspects of the project. A CAB can provide feedback on 1) developing research questions; 2) developing recruitment plans; 3) reviewing survey questions or methods; 4) discuss ethical considerations that will arise during

the research project; 5) provide different perspectives of the data interpretation; and/or 6) recommend non-traditional dissemination methods. There should be plans to evaluate engagement with your CAB. For example, some teams periodically survey CAB members to determine if the meeting frequency and communication channels are helpful in keeping the CAB informed and provide feedback or to identify changes needed to keep members engaged over the course of the project.

CPPR Rigor

The spirit of CPPR calls for the appropriate involvement of a community Co-PI and broader community at all stages of the research process. There must be genuine community involvement, and consideration should be given to the extent that members of the community of interest are represented on the research team and/or CAB. Community involvement should align with the capacity and expertise of members and organizations involved in the project. The ethical treatment of community members and their data is paramount. A detailed data sharing agreement should be prepared and discussed (e.g., on the Collaborative Agreements form). The applicant team may contact the Program Officer who will administer this grant type to discuss questions about the appropriate involvement of community members in a CPPRA application.

To support the scientific rigor of the CPPRA project, the applicant should not allow Co-PIs, CAB members or anyone who is shaping and implementing the project to have conflicting roles. For example, a CAB member should not be enrolled as a participant in the project. Research staff who are carrying out the project, whether they represent the community or academic perspective, should not also serve as research participants.

Partnership, Collaboration, and Community Engagement

The CPPRA team has the opportunity to describe (via Collaborative Agreements Form) how they will work together and share power, budget, resources, and outcomes with each other. In addition to the community Co-PI and academic Co-PI the project team can include additional co-investigators, consultants, collaborators and mentors to ensure appropriate community and academic expertise is included on the research team. Co-PIs should describe their decision-making plan to inform reviewers how consensus or agreement will be obtained for decisions that impact the research project. The team must ensure that the community and academic budgets are equitable and accurately reflect the effort contributed to the project by team members.

Dissemination and Sustainability

Applicant teams must develop a dissemination plan and a sustainability plan. To effectively disseminate research findings, plans to train individuals or present findings to community members and/or CBOs through in-person meetings or webinars can be appropriate. In addition, teams should describe the applicability of their research findings to other communities in California and include a plan for broader dissemination beyond their immediate communities.

In the sustainability plan, efforts to continue the partnership activity after the life of the pilot phase of funding should be developed. Plans to evaluate the partnership over time can provide

useful information on how to sustain the collaborative work. Early identification and utilization of community assets can also inform partnership sustainability and dissemination channels for findings. Plans for capacity building and maintenance on both sides of the partnership can be described in the proposal.

Pilot CPPRA REVIEW CRITERIA

Criteria Set-1 (40 percent scoring weight) "Research"

- **Statement of Goals, Research Questions, and Specific Aims**: Are the goals for the Pilot award clearly stated, achievable, and considered within the context of the partnership's longer-term research goals? Will the Pilot research activity prepare the collaborative team to pursue further research and to apply for a TRDRP Full CPPRA Research award (available in a future cycle) or funding from another agency? Are the research questions clear and appropriate for a community-partnered participatory Pilot award? Are the Specific Aims clear and encompass a reasonable amount of research activity for a Pilot study? Is there a logical connection between Aims and a relationship to the team's long-term research goals?

- **Background, Significance, and Relevance to a Tobacco-Related Area:** Are the communities/schools of interest clearly described? Does this study address an important tobacco-related problem? What is the evidence that the stated problem is of concern in the community(ies)/schools of interest? Is relevant literature summarized, synthesized appropriately, and does it support the proposed research activity? Is/Are the rationale underlying the proposed research question(s) well-supported and appropriately contextualized? Is/Are the pilot level of research activity appropriate to begin addressing the stated tobacco-related research question(s)? Is there evidence that the community-based organization or community members were involved in identifying and conceptualizing the research problem and research project?

  Research Plan: Research Design, Conceptual Framework, and Data Analysis Plan: Are the conceptual or theoretical framework, design (including composition of study population and strength of recruitment plan), methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project and the nature of the pilot grant type? Does the applicant clearly describe relationships to be examined? Does the applicant team acknowledge potential problem areas and consider alternative strategies? Are the proposed sample sizes adequate to answer the proposed research question(s)? If an intervention is proposed, are the variables and relationships to be examined clearly identified and testable? Is a data analysis plan defined? Are project milestones well-defined with quantifiable measures that are appropriate for assessing the success of the pilot phase award? Is the proposed work feasible? Is the research design aligned/consistent with the capacity and expectations of the community and community-based organization (e.g., whether a randomized controlled study design violates community or community-based organization norms)?

Criteria Set-2 (40% scoring weight) "Partnership"

- **Partnership Collaboration Plan and Team Communication Process:** Are the collaborative agreements clear and likely to lead to project success? Is the communication plan adequate to keep the community-based organization, Community Advisory Board (CAB), or school updated on the research? Are there plans to seek input and guidance from the CAB? Is there a clear decision-making process for important project activities? Will the team monitor or evaluate the health of the community-academic partnership over time? Are plans to evaluate the strengths and weaknesses of the community-academic partnership over time meaningful and likely to be useful?

- **Potential for the Proposed Work to Benefit the Community and Lead to an Intervention:** Is there potential for the proposed research activity to impact tobacco-related health disparities in a priority group in California? Will the community/school; community participants/students, staff, or faculty; academic institutions or community-based organizations; and their investigators benefit from the anticipated outcomes of the proposed research? Does the pilot research activity have potential to lead to development of a prevention or treatment intervention, school-based curriculum, policy implementation, improve clinical services, or inform anti-tobacco programming at a future time, even if additional funding is needed?

- **Community Engagement and Capacity Building:** Does the applicant team propose a sound approach to engaging communities affected by tobacco use in either their collaborative partnership or by proactively informing about the nature and significance of the research and research outcomes? Will the team obtain feedback from the community or community-oriented academics about the project and its findings? Will the project build capacity in the community, school, or community organization for future research, improved tobacco-related service delivery or clinical practice change, or tobacco control programming? Does the dissemination of findings include channels and tools targeting clinicians, public health practitioners, educators, advocates, policymakers, or the general public?

- **Dissemination Approaches and Sustainability Plan**: Are there plans to disseminate findings from the project to the community of interest? Will the community Co-PI or the CAB be involved in interpreting research findings or comprehending what findings mean for the community? Are there plans to disseminate findings using channels and tools readily accessible and known by the community? Are there plans to inform the community of resources made available or improved by the findings from the proposed research? Are there plans to sustain the community-academic research partnership after the pilot funding?

- **Statement of Future Goals:** Are future research goals clear and reasonable, and do they consider perspectives from the community of interest? Are the plans to apply for follow-on grant funding convincing? Could the research activity in the pilot award contribute to a future intervention focused on tobacco prevention or cessation or policy change?

Criteria Set-3 (20% scoring weight) "Resources"

- **Investigative Team:** Are the co-principal investigators and other key personnel listed in the grant proposal appropriately trained and well-suited to conduct community-partnered participatory research? Are the roles and responsibilities of the partners clearly defined? Will the research process allow academic researchers to learn more about the community or school and will community/school members learn about the academic research process? Is the work proposed appropriate to the experience level of the co-principal investigators and other co-investigators (if any)? Do the investigators demonstrate access to the research population of interest?

- **Environment, Facilities, and Resource Availability:** Will the community or school locations in which the research will occur contribute to the probability of success? Does the proposed pilot project utilize unique features of the community, school, institutions, or organizations involved in the research and/or utilize useful collaborative arrangements to resource the project? Is there evidence of academic institutional support and community- or school-based organizational support?

- **Community Assets**: Are community-level assets, strengths, and access channels well-described, appropriate for the study design and research question(s), and likely to contribute to the success of the pilot work? Is the project likely to contribute to strengthening existing community assets for tobacco control? Is there evidence of credibility of the partnering community-based organization within the community of interest, a track record of success in delivering services or programs in the community, and representation by a specific priority population within the organization?

Additional Review Criteria

Reviewers will evaluate the following additional items while determining scientific and technical merit, but will not give separate scores for these items.

- **Budget:** Appropriateness of the budget request for the project, scientific, or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project

- **Protection of Human Subjects from Research Risk:** If human subjects are involved in the research, protections from research risk relating to their participation in the proposed research will be assessed. Applicants must describe efforts to protect people from potential risks/ side effects of study participation and processes to ensure ethical treatment of all human participants involved in the study. Please complete all sections of the human subjects form to describe the ethical treatment of participants and their data at all stages of the Pilot study.

- **Appropriate Inclusion of Women, Minorities, and Children in Research**: If human participants are involved in the research, the adequacy of plans to include participants of all genders, all racial and ethnic groups (and priority groups), and children as appropriate

for the scientific goals of the research will be assessed. Plans for the recruitment and retention of participants will also be evaluated.

- **Care and Use of Vertebrate Animals in Research:** If vertebrate animals are involved in the project, plans for their care and use will be assessed.

FORMATTING REQUIREMENTS AND IMPORTANT REMINDERS

Formatting Requirements

All application content must be in **English**. Follow these format requirements for submitted written text, which are consistent with the NIH's 398 form instructions:

- The height of the letters must not be smaller than 11 point. Times New Roman or Arial are the suggested fonts.
- Line spacing is single spaced, and must no more than 6 lines of type within a vertical inch.
- Type density, including characters and spaces, must be no more than 15 characters per inch (cpi)
- Page margins, in all directions, must be at least ½ inch.

Deviations from the page format, font size, specifications and page limitations, especially the page limit for the Research Plan, will be grounds for the TRDRP to reject and return the entire application without peer review.

Important Reminders

- Each Co-PI must be registered with SmartSimple (see SmartSimple instructions) and must select an institution with a tax ID (EIN) number.
- Other Documents Necessary to Review Prior to Submission: TRDRP Call for Applications— pertains to all award types
- Technical Assistance is Available: For many community groups and scientific researchers, collaborations of this type are new and a bit confusing. Community groups may also be unfamiliar with the scientific research award process and the online application submission system. Please feel free to email Norval Hickman, Ph.D., at Norval.Hickman@ucop.edu or RGPOGrants@ucop.edu to request technical assistance. Our staff is not involved in the scoring process; any questions you ask will not affect the evaluation of your application in any way.

Application Instructions

Please review the "SmartSimple Application Instructions" for the technical instructions for accessing and completing your application. This supplemental programmatic instruction document provides guidance for the content of your application.

Section 1: Title Page

- **Project Title:** Enter a title that describes the project in lay-friendly language. (Max 100 characters)
- **Project Duration:** Enter a project duration (1-2 years)
- **Proposed Project Start Date:** Enter a project start date of July 1, 2020
- **Proposed Project End Date:** Enter a project end date of June 30, 2021 for a one year award; December 31, 2021 for an 18 month award; or June 30, 2022 for a 2 year award.

- **Out-of-State Expenses:** Indicate whether there are any out-of-state expenses associated with the proposal.

Section 2: Applicant/PI

A required field entitled "ORCID ID" is editable on the Professional Profile Page. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between you and your professional activities ensuring that your work is recognized. If you have not already obtain an ORCID ID number, you may do so here: http://orcid.org/ Once you have done so, please enter your 16-digit identifier in the space provided on your profile page in the following format: xxxx-xxxx-xxxx-xxxx.

Section 3: Project Information

Please use the following guidelines to differentiate between Lay and Scientific Abstracts:

- **Lay Abstract:** This item is evaluated mainly in the programmatic review. **The text is also entered in the appropriate box in the "abstracts" page of the Proposal Sections.** Do not use symbols or other special text, as these will not transfer to the "abstracts" box. The **Lay Abstract** must include the following sections:
  - A **non-technical introduction** to the research topics
  - The **question(s) or central hypotheses** of the research in lay terms
  - The **general methodology** in lay terms
  - **Innovative elements and potential impact** of the project in lay terms

The abstract should be written using a style and language comprehensible to the general public. Avoid the use of acronyms and technical terms. The scientific level should be comparable to either a local newspaper or magazine article. Avoid the use of technical terms and jargon not a part of general usage. Place much less emphasis on the technical aspects of the background, approach, and methodology. Ask your advocate partner to read this abstract and provide feedback.

- **Scientific Abstract:** This item is evaluated mainly in the peer review. Do not use symbols or other special text, as these will not transfer to the "abstracts" box.

The Scientific Abstract should include:

- A short introductory paragraph indicating the **background** and overall topic(s) addressed by the research project
- The **central hypothesis** or **questions to be addressed** in the project.
- A listing of the **objectives or specific aims** in the research plan
- The major research **methods and approaches** used to address the specific aims
- A brief statement of the **impact** that the project will have on tobacco.

Provide the critical information that will integrate the research topic, its relevance to tobacco, the specific aims, the methodology, and the direction of the research in a manner that will allow a scientist to extract the maximum level of information. Make the abstract understandable without a need to reference the detailed research plan.

Applicants must respond to the following categories, unless otherwise noted, and discussion points using the online fields provided:

- **Specific aims** (approx. 350 words). List the proposed aims of the project.
- **Focus on tobacco-related research.** Yes/No.
- **Keywords.** Between three to five keywords that best reflect your research for use in peer review selection
- **TRDRP Research Priorities**. Name the TRDRP priority issue that the research addresses.
- **CSO Research Type(s and Sub-Type(s)**. See SmartSimple submission instructions for more details
- **Subject Area(s).** See SmartSimple submission instructions for more details
- **Focus Areas(s).** See SmartSimple submission instructions for more details
- **Research Demographics.** Complete this table if the research project will involve human subjects. Enter the target demographics of the research participants that you propose to recruit (optional).
- **Milestones.** Add significant milestones that are described in your research plan to this table along with anticipated completion dates and arrange them in chronological order.
- **Suggested Reviewers.** Enter suggested reviewers to serve on the committee (optional).

Section 4: Project Contacts

- **Project Personnel.** Provide contact information and effort for ALL personnel on your project including the Applicant Principal Investigator, Co-Investigator, Advocate, Trainee, Collaborator, Consultant, and support personnel. Upload biosketches to each of your Key Personnel members in this section, as shown in the SmartSimple instructions.

Section 5: Budget

This section contains five sub-tabs: Institution Contacts, Budget Summary, Budget Details, and Subcontract Budget Details. Complete the information in the Institutional Contacts, Budget Summary, Budget Detail and, if applicable, Subcontract Budget Details tab as described in the SmartSimple Application Instructions.

Each institution that is a partner in the project must complete a budget. This means the Community Co-PI and the Academic Co-PI will each have their own Budget. If a collaborative partner on the project has a subcontract, then that subcontracting organization can complete a budget or the prime partner can complete the budget for the subcontracting organization.

Applicants should ensure that the direct costs on the Budget tab do not exceed the cap on the award type.

Note: *Prime-Subcontractor relationships between two partners on a CPPRA grant will be rare. In the event that you have discusses this structure with the Program Officer for CPPRA awards, and have determined that you can select the Prime-Subcontractor structure, the following policy applies: The amount of the subcontracted partner's F&A costs can be added to the direct costs cap. Thus, the direct costs portion of the grant to the recipient institution may exceed the award type cap by the amount of the F&A costs to the subcontracted partner's institution.*

Contact the CPPRA Program Officer, Norval Hickman, Ph.D., M.P.H. with any questions (Norval.Hickman@ucop.edu; 510-987-9032).

- Budget Guidelines:

The **maximum duration is 2 years and the direct costs budget cap is $400,000**.

> **Note:** The amount of the subcontracted partner's F&A costs can be added to the direct costs cap. Thus, the direct costs portion of the grant to the recipient institution may exceed the award type cap by the amount of the F&A costs to the subcontracted partner's institution.

- **Personnel.** Describe the duties of each person and the specific role each will perform in this project, and justify by category all requested expenditures. List by name and job title all personnel who will participate in the project, if known; if not known, use the position title. When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income.
  Graduate students may be paid as personnel and may also receive tuition remission from awards. Tuition remission in this circumstance, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition) allowable will be $35,568 per year per FTE. There are no constraints on how this amount is divided between salary and tuition.
- **Equipment purchases up to $10,000 are allowed.** Only include individual items >$5,000. Any items less than $5,000 must be purchased under the "supplies" budget category.
- **Supplies and expenses.** All other project costs.
- A minimum of $750 must be budgeted in year 1 for travel to the TRDRP Symposium or Conferences under **RGPO Meeting**.
- **Scientific meeting trave**l is capped at $2,000/yr.
- **Indirect (F&A) costs**. Indicate the F&A rate chosen, whether the rate is a DHHS negotiated rate, a rate established by some other means or authority, or the de minimus rate of 10%. Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 30% MTDC*, or 26% MTDC for off-campus investigators (not retroactive to prior grants).

**Allowable expenditures in the MTDC base calculation include salaries, fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from the modified total direct cost base calculation*

Additional budget guidelines can be found in Appendix D of the SmartSimple Instructions for CPPRA Awards.

Section 6: Assurances

Enter assurance information. If available, enter your institutional Federal Wide Assurance (FWA) code or equivalent for Human Subjects, an IACUC Animal Welfare Assurance code for Vertebrate Animals, and equivalent for Biohazard ad DEA Controlled Substance approvals.

Section 7: Documentation

The award-specific and TRDRP General Application Requirements instructions are located here. All required items to complete and upload are listed. All uploads must be in PDF format. Listed below are the

forms and templates you download from SmartSimple, enter text, convert to PDF, and, unless instructed otherwise, re-upload to your application in this section.

Upload Item (Template/Form)	Page limit	Required or optional
Collaborative Agreements	**3**	**Required**
Community Advisory Board	**2**	**Required**
Biosketches (All Personnel listed on Key Personnel form)	**5 (each biosketch)**	**Required**
Facilities	**1 per institution**	**Required**
Research Plan	**12 + references**	**Required**
Human Subjects	**No limit**	**Required**
Vertebrate Animals	**No limit**	**Optional**
Appendix list and uploads	**30**	**Optional**

DETAILED DESCRIPTION OF PROPOSAL TEMPLATES

Instructions – COLLABORATIVE AGREEMENTS (required)

This form is used in Peer Review in part to score the "Partnership" criteria.

Limit the text to three pages: To be Prepared by the Community and Academic Partners. Remove descriptive text to ensure sufficient space for a thorough response to each section.

The **Community Applicant** is required to verify the decision process addressed in this form by submitting a statement that the governing body representing their Community-Based Organization (e.g., Board of Directors) has reviewed and approved this agreement. The **Academic Applicant** is responsible for ensuring the decision process addressed in this form is acceptable to and enforceable within their appointment at their research institution and is in accordance to policies at the research institution where they hold their appointment.

Ownership of Data. Describe the applicant team's decision about who will own the data, the timeliness within which data will be shared with their partner, acceptable uses of data from this proposed project, and intellectual property rights AND how the team derived the decision (i.e. what factors you considered, what was important to you in making this decision). If the applicant team decided that the data will be owned by only one of the collaborators, please consider that the need to continue to work together will likely extend well beyond the grant period. Will the partner who owns the data be willing to volunteer their time well after the grant period to provide access to the data for the other partner? Be sure to discuss ownership of identified and de-identified data, how IRB and the ethical treatment of participant data will be managed, and include arrangements both partners have agreed to that ensures access to the data by the other partner (including beyond the study period).

Handling Disagreements. Describe the process you will go through to manage disagreements that might arise during the study and afterwards. Occasionally, community-academic research teams have had to resolve issues around data ownership, conduct of the research, exclusion/inclusion criteria, addressing the needs of the community, cultural humility, dissemination of data and manuscript preparation for publication, administrative and budget issues. Describe how your decision process and resolution plan will work for your team.

Recipient of Grant Award. Describe the process your team went through to determine whether the grant award will be contracted directly to one partner or to both partners and the rationale supporting the decision. TRDRP suggests that if both applicant agencies have the administrative capacity to manage grant awards, that each agency receives a separate award and manage their own portion of the budget.

Plans for Broader Community Involvement in ALL phases of the Research Project. Describe how individual community members not on the research team or community-based organizations not involved in the project (e.g., staff or board of a community agency) will or might be involved in the planning, conducting, evaluation, or dissemination of the research activities and study findings. Describe how the broader community participation will be overseen by the co-principal investigators and research team.

Team Communication Plan. Describe the frequency and modes of communication that will be utilized to ensure the co-principal investigators stay abreast of the research progress and challenges when they arise. Describe how the community Co-PI and their community organization will communicate with one another to facilitate input and decision-making. Describe how the academic Co-PI and their research institution will communicate with one another to maintain buy-in and support for the project and ensure the research adheres to institutional policies and best practices for academic research.

Decision-Making Process for Community and Academic Co-PIs. Develop and describe a multiple PI decision-making process and plan. Given their might be multiple co-investigators, consultants and collaborators, in addition to the community Co-PI and academic Co-PI, involved in the proposed research project, it is imperative that a plan is in place that considers multiple perspectives from the research team and leads to a consensus or majority decision. Describe how project-related decisions will be finalized. A decision-making process that clarifies whether consensus-making or another decision tool will be used is recommended. Describe why the decision-making plan is well-suited for your research team and how it can contribute to the success of the project.

Plans for Turn-over of Personnel. Describe how the turn-over of personnel at the community or academic sites will be handled. Describe how the community Co-PI or academic Co-PI will interact with their respective institutions if a replacement is needed, and what steps will be taken to select a replacement community Co-PI or academic co-PI if that were to be needed. Please keep in mind that the replacement of the community Co-PI, community-based organization, academic Co-PI, and academic research institution will need to be approved by TRDRP in accordance with the process detailed in the Grants Administration Manual available on the RGPO website https://www.ucop.edu/research-grants-program/grant-administration/index.html.

Plans to Evaluate the Strength of the Research Partnership. Attention to building and strengthening community-academic research partnerships is critical to the success of community-based research and the longevity of the collaborative effort. Describe the strategy your team will implement to evaluate how the partnership develops over time. Issues to consider include frequency and method of communication; meeting location - will meetings be held in the community, university, both sites, or alternative locations; and frequency and method of sharing information. Consider creative evaluation tools that include qualitative, quantitative, and technology-driven information gathering methods and monitors changes in knowledge, attitudes, and behavior over time.

Plans for Dissemination of Findings. Dissemination of research findings to both the lay community and the scientific community is important to this research award. This is sometimes a difficult issue as scientific dissemination is often a lengthy process and may impede community dissemination. Please describe what agreements have been made as to how research findings will be disseminated to both the community of interest and the scientific community and the expected timing of dissemination.

Plans to Sustain the Research Partnership Beyond the Life of the Grant. Community-partnered participatory research requires consideration of the longer-term impact a community-academic collaborative research team can have in their community of interest. While challenging to know exactly how long the research partnership will last, describe, according to best intentions, how the research partnership could continue after the life of the pilot phase of funding, regardless if there are continued funds or no continued funding streams. Please consider that many multiple underserved communities in California have experienced research teams collecting their data, but not reporting back to the community nor using findings to improve health-related programs or policies in the community.

Instructions – COMMUNITY ADVISORY BOARD (required)

Limit the text to two pages.

The Co-PIs should use the Community Advisory Board application form to describe the composition of CAB members at the time of application submission. Co-PIs should list name, organization affiliation and expertise for CAB members that have been confirmed at time of application submission. The applicant team may describe eligibility criteria used for recruited and current CAB members, how the team proposes to engage with their CAB, how frequently the CAB will be convened, whether payment or other incentives will be provided. Describe how the research partners plan to communicate and interact with Community Advisory Board members. The communication between the applicant team and CAB should be evaluated or monitored with plans to modify as needed. An evaluation tool that monitors strengths and weaknesses of community-academic partnership over time is recommended. The CAB does not have to be fully comprised at time of submission. A letter of collaboration from recruited CAB members or the committee chair is advised and should be included in the Appendix section.

Instructions – BIOGRAPHICAL SKETCH (required)

Limit the text to five pages.
Complete a biographical sketch for each person listed in the Key Personnel section only, beginning with the co-principal investigators. Limit each sketch to five pages. Do not send reprints or manuscripts as part of this form. Corresponding NIH forms are acceptable (NIH Form SF424R-R_biosketch_VerC or later).

Biosketch Includes:

- **Personal Statement:** Briefly describe why you are a good fit for the project team, based on your experience and qualifications. Describe in a few paragraphs what specific strengths you bring to the project, relevant to the collaboration, community-connectedness, scope, aims and methods of your application.
- **Positions & Honors**
    - **Education/Training:** Begin with baccalaureate and end with the most recent, including postdoctoral training.
    - **Research and/or Professional Experience:** List positions in chronological order.

- **Honors:** List awards or honors received in chronological order. This can include awards for community based or academic efforts that are relevant to the current application. You can include membership in advisory committees (including those for the federal government).

- **Contribution to Science:** Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.
- **Research Support:** List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). *Begin with the projects that are most relevant to the research proposed in the application.* Briefly indicate the overall goals of the projects, the responsibilities of the key person identified on the Biographical Sketch, and the percent effort for the key person. Do not include number of person months or direct costs. ***We require that you add percent effort to the format provided in the NIH Biosketch Instructions, i.e.:***

R01 DA942367 Hunt (PI) 09/01/08-08/31/16

Health trajectories and behavioral interventions among older substance abusers

The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.

Role: PI, **10% effort**

Instructions – FACILITIES (required)

Limit the text to one page. Follow the instructions on the template.

Instructions – RESEARCH PLAN (required)

Limit the text to 12 pages.
Page limits are exclusive of bibliographical references, which should follow the research plan.

Follow the formatting instructions in “General Items” above.

Both co-principal investigators’ names (last name, first name, middle initial) must be printed in the upper right-hand corner of every page.

We ask that applicants describe the proposed research project in sufficient detail for reviewers to evaluate its scientific merit and collaboration elements, as described below. If you don't use all the pages to describe your research plan, it might be best to review what you have written and explain in more detail anything not fully explained. **However, note that a concise, focused research plan of less than the maximum number of pages is preferable to one less concise and made longer by overly elaborate or unimportant details.**

Supporting materials (such as questionnaires, consent forms, interview questions, letters of collaboration) that are directly relevant to the proposal may be included in the **Appendix**. **The research plan must be self-contained and understandable without having to refer extensively to supporting materials.**

Special Note: The content below is included to guide your thinking process when preparing the Research Plan. There is no requirement to address each topic or question, but rather it should inform the collaborative discussion among research team members. Addressing each topic does not guarantee your application will be funded. Applicant teams should focus on topics most relevant to their research question(s) and approach(es).

Statement of Goals, Research Questions, and Specific Aims: Describe the goals for the Pilot phase of funding considering the long-term research goals, partnership development, and community involvement. Describe how the Pilot, if awarded, will be used to prepare the collaborative team to pursue further research and to apply for a TRDRP Full CPPRA award (available in a future cycle) or funding from another agency. State the research question(s) for the Pilot award. Follow with the Specific Aims—the specific tasks and research-related activities that will be undertaken to address the question(s). These should have a logical connection, and you need to make clear their relationship to the team's long-term research goals. Do not include tasks that you expect to undertake in the Full CPPRA Research award project or with future funding from another agency.

Background, Significance, and Relevance to a Tobacco-Related Area: Begin this section by describing the community of interest for this study. Is the community distinct because of geography, age, gender, associated by disease status or risk, race, sexual orientation, or socioeconomic status? Describe the interest of the community or community-based organization in the research problem and research project and how they have participated in identifying it. Discuss the importance and benefit to the community of the research question(s) and expected outcomes. Specifically answer how the broader community of interest was involved in developing the research proposal.

Concisely describe the rationale underlying the proposed research and provide support that the research question(s) are important for the community of interest. Position the research in the context of existing relevant scientific literature and community knowledge on the tobacco-related area and preliminary information that the team may have collected in preparing for the project. Demonstrate a grasp of the current scientific and community knowledge relevant to the tobacco-related problem. Provide up-to-date references, acknowledge controversies and contradictory reports, and be comprehensive and accurate. If there is little literature on the topic, draw on information from related fields. Describe the community interest, community's or community-based organization's participation in the plan development from the beginning, and potential contribution to the proposed research project, if funded. Keep discussion of the general problem of tobacco-related disparities brief; emphasize the specific problem addressed by your research proposal.

Research Plan: Research Design, Conceptual Framework, Approach, and Data Analysis Plan: Describe in detail the exact tasks associated with the Statement of Goals, Research Questions, and Specific Aims. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. Provide a theoretical or conceptual framework or model that informs

the study design and research activities. Describe the methodology to be employed; how feasibility and acceptability will be determined (i.e., what measures will be used); if appropriate, the hypotheses to be investigated; and the methodologic approach (or possible approaches that seem at present most appropriate to be used). For example, if adolescents are to be surveyed, explain how many adolescents will be surveyed; rationale supporting sample size(s); how adolescents will be identified and recruited; why you believe you will be able to reach and recruit the estimated number of adolescents; what questions you will ask them; whether you will use face-to-face or telephone interviews, or written surveys and why you will use the method chosen; and, how the data will be collected and analyzed. Be as detailed as possible. Provide this information for each specific task cited in the first section. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fully realized. Provide a realistic timeline. Clearly state a collaboratively prepared data analysis plan that will adequately address Specific Aims. Include milestones, with quantifiable measures, anticipated over the course of the research project. Demonstrate that the research design is aligned/consistent with the capacity and expectations of the community and community-based organization (e.g., whether a randomized controlled study design violates community or community-based organization norms).

Partnership Collaboration Plan: Describe the relationship between the community Co-PI and their community organization and the community of interest. How will the community of interest be represented on the research team? Discuss how the leadership of the community organization (e.g., the Executive Director, the Board of Directors, or the individuals of an organization) will ensure that the organization or group is committed to the research project?

Describe in detail the plan for carrying out the collaborative research partnership. Describe your specific collaboration plans, including how and when the partners will interact; what the specific roles and responsibilities of each partner will be through each step of the research process; how all members will be brought into the design, data analysis, and decision-making process. Briefly summarize how the collaborative agreements (e.g., ownership of data, handling disagreements, how grant funds will be handled) described in more detail in the **Collaborative Agreements Form** will contribute to strengthening the partnership, the successful completion of Study Aims, and other project objectives.

Potential for the Proposed Work to Benefit the Community and Lead to an Intervention: Briefly state the long-term potential of the research: the problems, issues, or questions which, through the execution of this award, can be further developed, specified, and sharpened into testable hypotheses or provide formative work for a community-level prevention, policy-related, or treatment intervention at a future time. Describe how the research partnership and findings could reduce tobacco-related disparities or benefit a priority group in California. Describe how the community/school; community participants/students, staff, or faculty; academic institutions or community-based organizations; and their investigators will likely benefit from the anticipated outcomes of the proposed research. While it is challenging to know what will be the outcomes of the research project, please consider and describe the potential for the proposed research activity to benefit the community of interest and contribute to formative work that leads to a community-level, tobacco-related educational or treatment intervention or policy change. Discuss how participating in this research project will build capacity for the community organization (such as through developing research/evaluation skills, answering a question important to the organization, having policy impact, improving programs or services), and the academic organization/investigator (such as demonstrating the value of community-partnered participatory research, contributing to a program of research focused on community participatory scholarly work, or justifying university resources for community-based research).

Dissemination Approaches and Sustainability Plan: Describe how the research partnership and findings will be broadly distributed and applicable to communities in California and how the community

will be involved in interpreting study outcomes. Describe efforts that will ensure the partnership activity will likely continue after the pilot phase of funding. If the aims of the pilot are achieved, describe plans for follow-on activities, such as plans to prepare and submit a full CPPRA grant application, application for another funding agency, plans to improve tobacco-related services or programming, or steps to routinely inform the community on outcomes of the study or build from where the study ends for community benefit.

Investigative Team: Describe how the experience, knowledge, and skills of the research team can contribute to the success of the research. Provide evidence that the co-principal investigators and other key personnel are appropriately trained and well-suited to carry out the research. Be clear about the roles and responsibilities of the research partners. Highlight experience and successes working with the community of interest. Describe what is expected to be learned by the collaborative research team during the study.

Environment, Facilities, and Resource Availability: Describe how the community or school locations in which the research will occur can contribute to the success of the research project. Highlight resources and access that the community partner and community-based organizations will provide that will encourage success of the project. Describe resources available through the academic Co-PI that will uniquely benefit the pilot project. Demonstrate access to the research population of interest.

Community Assets: Describe community-level assets, strengths, and access channels the applicant team proposes to utilize over the course of the study or during the dissemination phase. Describe how the project will contribute to building capacity in the community of interest for future research, policy change, or programming activities. Provide evidence of credibility of the partnering community-based organization within the community of interest, a track record of success in delivering services or programs in the community, and representation by a specific priority population within the organization.

Statement of Future Goals: Begin with a brief discussion of the long-term research goals of the team, as well as a description of the work the team would like to pursue with a TRDRP Full CPPRA or funding from another agency after completing the Pilot award. Describe how the research findings from the pilot could potentially inform a future intervention focused on tobacco prevention or cessation, policy change, or improvements in tobacco-related services and programs. Be as specific as possible about future research plans.

Instructions – HUMAN SUBJECTS (required)

This form is required for all applications but only needs to be completed if the proposed study will involve human subjects.

Special Note to CPPRA Applicants: If you are planning on having data from your studies with individual identifiers being accessible and possibly even maintained by both the Community Research Partner and the Academic Research Partner, please address this issue in your Human Subjects approval application. If you received Human Subjects approval through one partner's IRB, and you did not include in the IRB application that the other partner will receive a copy of the identified data during or after the study, you may be precluded from sharing the data.

Provide sufficient information in response to item (1) below to confirm there has been a determination that the designated exemptions are appropriate. Determination of exemption from DHHS regulations must

be made by an approved Institutional Review Board (IRB). Documentation of IRB review must be provided before an award is made. Research designated exempt is discussed in the U.S. Department of Health and Human Services, Public Health Service Grant Application #398 Part II Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Pages 4-5. Although a grant application is *exempt* from these regulations, it must, nevertheless, **address the issues of race/ethnic composition of the subject population**, as instructed in item (2) below.

If your proposal will involve human subjects, and you have not applied for or received an exemption, you must address the seven points below. In addition, when research involving human subjects will take place at collaborating site(s) or other performance site(s) provide this information before discussing the seven points. Although no specific page limitation applies to this section, be succinct.

1. Provide a detailed description of the proposed involvement of human subjects in the work outlined in the research plan.

2. Describe the characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and the TRDRP that research involving human subjects must include males, females, and members of minority groups in study populations. Applicants must describe how racial/ethnic minorities will be included as research participants and identify the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. For example, adequate inclusion of minorities as subjects in research studies may be impossible or inappropriate with respect to the purpose of the research, due to the health of the subjects, or for other legitimate scientific reasons. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated. It is not necessary in this application to document inclusion of women.

3. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained and who will seek it, the nature of the information to be provided to the prospective subjects, and the method of documenting consent. State if the IRB has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

5. Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

6. Describe the procedures for protecting against, or minimizing, any potential risks (including risks to confidentiality), and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects. Also where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.

7. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of knowledge that may be reasonably expected to result. If a test article (investigational new drug [IND], device, or biologic) is involved, name the test article and state whether the IND has been obtained.

Documentation of Assurances for Human Subjects
In the Appendix to your application, include official documentation of the approval by the IRBs of all participating institutions, if available at the time of submission, showing the title of this application, the principal investigators' names, and the inclusive approval dates; do not include supporting protocols. IRB approval is not required at time of application submission

Approvals obtained under a different title, investigator, or organization are not acceptable, unless they cross-reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, a USPHS-approved IRB must provide the assurance. If review is pending please note that and send the final assurance as soon as possible to TRDRP. Funds will not be released until all assurances are received by the TRDRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, approvals from the boards of each will be required.

Instructions – VERTEBRATE ANIMALS (optional)

This form is required ONLY for applications involving vertebrate animals.

If your application involves vertebrate animals the following five points must be addressed. When research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. Although no specific page limitation applies to this section of the application, be succinct.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the research plan. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.

4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If it is not, present a justification for not following the recommendations.

Documentation of Assurances for Vertebrate Animals
Grants will not be awarded for research involving vertebrate animals unless the program for animal care and welfare meets the standards of the AAALAC or the institution has a U.S. Public Health Service assurance. In the appendix, if available at the time of submission, include official documentation of institutional review committee approval showing the title of this application, the principal investigator's name, and the inclusive approval dates; do not include supporting protocols. Approvals obtained under a different title, investigator, or institution are not acceptable unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to the TRDRP as soon as possible. Funds will not be released until all assurances are received by the TRDRP.

Instructions – APPENDIX COVER SHEET (required; contents optional)

The research plan must be self-contained and understandable without having to refer to the appendix. Only those materials necessary to facilitate the evaluation of the research plan may be included; the appendix is not to be used to circumvent page limitations of the application. No supplemental materials are allowed after the submission deadline unless requested by the TRDRP. While there are no page limits for the appendix, we strongly recommend that the appendix be no more than 30 pages in length.

ALL APPENDIX MATERIALS will need to be "uploaded" to the SmartSimple website (so therefore in PDF format). If the applicant plans to attach print materials (brochures, handbooks, etc.) they are advised to begin preparing those documents in uploadable formats well before the application deadline.
Community Agency Resolution. Provide a copy of a resolution or the section of minutes from a meeting of the Community Applicant governing body (Board of Directors for a nonprofit organization or the individuals responsible for organizing an informal organization) indicating their review and agreement with the details outlined on the Collaborative Agreements form. The resolution or minutes should include the date of approval and should be signed by an officer of the organization.

Letters of Collaboration can be important in showing support for the research project from the community. The letters should be as specific as possible in describing the specific involvement of the individual or organization in designing the research project or the anticipated involvement in working with the collaboration in carrying out the research. General letters of support, without addressing the specific involvement of the individual or organization in the research project, are not as important as letters of collaboration, showing anticipated involvement in the project. **ALL LETTERS SHOULD BE COMBINED INTO ONE PDF DOCUMENT; DO NOT UPLOAD INDIVIDUAL LETTERS OF COLLABORATION.**

Supporting Documents. Supporting materials (such as questionnaires, consent forms, interview questions) that are directly relevant to the proposal may be included in the Appendix. Note that the research plan must be self-contained and understandable without having to refer to the Appendix. Only those materials necessary to facilitate the evaluation of the research plan may be included: the Appendix is not to be used to circumvent page limitations. Please itemize materials on the Appendix Cover Sheet.

Resubmission Guidelines. Submission of a revised CPPRA application is not applicable in the 2020 cycle for the Community-Partnered Participatory Research award funding opportunity. TRDRP's policy's regarding multiple submissions apply to the CPPRA award type.

TRDRP FUNDING POLICIES AND PROCEDURES

Resubmission Policy

A resubmission is an unfunded application that was submitted to TRDRP as a new application in the previous year and resubmitted under the current Call for Applications. TRDRP will accept only a single resubmission of the same or very similar project, regardless of change in application title. Resubmissions are only allowed once and must be submitted in the subsequent Call for Applications.

Please note the following exception: applications originally submitted in grant cycle 2019 A, and not resubmitted in grant cycle 2019 B, are eligible for resubmission in response to this 2020 Call for Applications.

Applicants are still required to inform TRDRP of their intent to resubmit through an LOI submission, and must note it as a resubmission (please refer to the LOI/Application instructions for the specific award type). All other applications are considered new applications.

Multiple Submissions Policy

Researchers can submit more than one application, provided that the proposed research topics and aims are significantly different for each LOI/application.

TRDRP Eligibility Criteria

Investigators from California not-for-profit organizations are eligible for TRDRP funding, including but not limited to colleges, universities, hospitals, laboratories, research institutions, local health departments, community-based organizations, voluntary health agencies, health maintenance organizations and tobacco control organizations. The sponsoring institution, in accordance with its own policies and procedures, should designate the co-principal investigator (Co-PI). The Co-PI must supervise the research project and any trainees directly and in person. U.S. citizenship is not a requirement for eligibility.

In accordance with UC policy (https://policy.ucop.edu/doc/2500500/ReqSubmitProp-Awar), PIs who are UC employees and receive any part of their salary through UC must submit grant proposals through their UC campus contracts and grants office. Exceptions must be approved by the UC campus where the PI is employed.

Applicants at California-based Nonprofit Institutions: TRDRP will accept applications from PIs at non-profit organizations or institutions, provided that the organization can manage the grant and demonstrate sound financial stewardship. The organization must also meet our liability insurance requirements. If the application is recommended for funding, the centralized business units within the Research Grants Program Office (RGPO) will collect additional information, such as tax ID numbers and financial reports, to review the organization during the pre-funding process to ensure all financial management and project management eligibility criteria can be met.

Applicant Appeal Policy and Procedures

The only basis on which an appeal regarding a decision concerning the funding of a grant application will be considered is the case of an alleged error in, or violation of, the peer review process and procedures. For example, the principal investigator may believe that he or she has a conflict of interest with a member of the review panel that was not known to the program at the time of the review. Appeals based on substantive disagreement with the peer review evaluation will not be considered. In such cases, applicants may resubmit applications in a subsequent grant cycle.

Before submitting appeals, applicants are encouraged to talk about their concerns informally with the appropriate program officer and program director.

Appeals must be submitted in writing to the vice president of Research and Innovation, University of California, Office of the President, within thirty (30) days of receiving the Summary Statement. The vice president may, if an applicant shows good cause, grant a reasonable extension of time for the submission of the request for review. The appeal must contain a complete statement of the basis for the appeal, including pertinent facts, supporting arguments, and documentation. If the application was submitted through an institution, the appeal must be submitted officially through that institution, and it must be signed by an official authorized to sign for the institution, as well as by the principal investigator. No appeal shall affect any authority of the University of California, Office of the President, the vice president of Research and Innovation, the executive director of the Research Grants Program Office, or the applicable program director.

Upon receipt of an appeal, the vice president of Research and Innovation shall decide if the dispute is reviewable under this appeals policy and notify the applicant, the program director and the executive director of the Research Grants Program Office of the determination. If the appeal is reviewable, it shall be transmitted to an appeal review committee appointed by the vice president. This committee will be comprised of two persons who are knowledgeable about both the type of research in question and the review procedures. The appeal review committee shall provide the applicant an opportunity to submit additional statements and documentation relevant to the appeal review committee's deliberation of the issues. The appeal will consider the application as submitted. Therefore, such supplemental appeals materials may not include additional data or clarification of the original application. The appeal review committee may, at its discretion, invite the applicant and any other person(s) to discuss the pertinent issues with the committee and submit such additional information as the committee deems appropriate. The committee may also request information from the program director regarding the review procedures or other issues raised in the appeal.

Participants in an appeal review (i.e., committee members and outside experts) and any materials considered will be subject to the same rules of confidentiality that govern the initial handling and evaluation of the application.

Based upon its review, the committee will prepare a written decision to be signed by the members. The appeal review committee shall send the written decision as advice to the vice president, who will render a final written decision and transmit it to the applicant, the members of the appeal review committee, the program director and the RGPO executive director. No further appeals within the University of California are available.

Submission Process

Submission of a Letter of Intent (LOI) is required to apply for all award types except for Community Partnered Participatory Research Pilot Awards, Rapid Response Research to Accelerate Policy Awards, and Award Supplements. The LOI must be submitted electronically. Applicants will have access to the application materials if the LOI is approved, at which time applicants will receive an email notification. LOI submission instructions should be strictly followed as stated.

All applicants should review the Call for Applications, LOI Instructions, and Application Instructions in their entirety, and must complete all necessary materials using the appropriate templates and forms. Failure to comply with provided instructions or submission of incomplete forms may result in administrative rejection of the application.

Review Process and Funding Decisions

Applications will be grouped by priority area and undergo peer-review by experts from outside of California. The criteria for evaluating applications are described under each specific award type section. TRDRP and its Scientific Advisory Committee will prioritize funding scientifically meritorious applications that are well-aligned with the priority areas described in this Call for Applications, that provide a balance across these priorities, and that are within the extent of funding that is available.

For more information about the funding process visit the TRDRP website (trdrp.org/funding-opportunities/review-process/index.html).

Publications Acknowledgement

All scientific publications and other products from a RGPO-funded research project must acknowledge the funding support from UC Office of the President, with reference to the specific TRDRP funding program and the assigned grant ID number.

Open Access Policy

As a recipient of a Tobacco-Related Disease Research Program (TRDRP) grant award, you will be required to make all resulting research findings publicly available in accordance with the terms of the *Open Access Policy* of the Research Grants Program Office (RGPO) of the University of California, Office of the President (UCOP). This policy, which went into effect on April 22, 2014, is available below:

RGPO Open Access Policy

The UCOP Research Grants Program Office (RGPO) is committed to disseminating research as widely as possible to promote the public benefit. To that end, all RGPO grantee institutions and researchers grant RGPO a nonexclusive, irrevocable, worldwide license to exercise any and all rights under copyright and in any medium for all scholarly articles and similar works generated as a result of an RGPO grant award, and agree to authorize others to do the same, for the purpose of making their articles widely and freely available in an open access repository. This policy does not transfer copyright ownership, which remains with the author(s) or copyright owners.

Scope and Waiver (Opt-Out)

The policy applies to all scholarly articles and similar works authored or co-authored as a result of research sponsored by an RGPO grant, except for any articles published before the adoption of this policy and any articles for which the grantee institution and/or researchers entered into an incompatible licensing or assignment agreement before the adoption of this policy. Upon express written request of the institutional grantee and/or researcher, RGPO will waive the license for a particular article or delay "open access" to the article for a specified period of time.

Deposit of Articles

To assist the RGPO in disseminating and archiving the articles, the grantee institution and all researchers on the grant will deposit an electronic copy of all publications in eScholarship (https://escholarship.org/), UC's open access repository promptly after publication. Notwithstanding the above, this policy does not in any way prescribe or limit the venue of publication.

Grant Management Procedures and Policies

All TRDCRP grant recipients must abide by other pre- and post-award requirements pertaining to Cost Share, Indirect Cost Rates, Monitoring & Payment of Subcontracts, Conflict of Interest, Disclosure of Violations, Return of Interest, Equipment and Residual Supplies, Records Retention, Open Access, and Reporting. Details concerning the requirements for grant recipients are available in a separate publication, the University of California, Office of the President, "***RGPO Grant Administration Manual***." The latest version of the Manual and programmatic updates can be obtained from the Program's office or viewed on our website: http://www.ucop.edu/research-grants-program/_files/documents/srp_forms/srp_gam.pdf

KEY DATES:

A letter of intent is not required nor available for the CPPRA grant type. You're encouraged to contact Norval Hickman, PhD, MPH with questions about applying for the CPPRA.

Fiscal Year 2020-2021	**TRDRP's 2020 cycle**
Direct access to application materials in Smart Simple	Beginning October 24, 2019
Due date for applications	March 5, 2020, 12p PDT
Applicants notified	June 2020
Award start date	July 1, 2020

Contact Information for Inquiries

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